IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

[SEALED],	§	Civil Action No. 18-2674
v.	§	
[SEALED].	§	JURY TRIAL DEMANDED
	§	FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730
	§	DO NOT ENTER INTO PACER
	§	DO NOT ENTER IN CM/ECF
	§	DO NOT PLACE IN PRESS BOX

FILED UNDER SEAL

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

United States of America ex rel. LYNDA PINTO, Relator,	§	Civil Action No.: _____
v.	§	JURY TRIAL DEMAND
CARDIAC IMAGING, INC, SAMUEL R. KANCHERLAPALLI, RICK P. NASSENSTEIN, Defendants.	§	FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)
	§	DO NOT ENTER INTO PACER
	§	DO NOT ENTER IN CM/ECF
	§	DO NOT PLACE IN PRESS BOX

COMPLAINT FOR DAMAGES UNDER THE FEDERAL FALSE CLAIMS ACT AND DEMAND FOR JURY TRIAL

I. PRELIMINARY STATEMENT

1. Relator Lynda Pinto brings this action under the Federal False Claims Act, 31 U.S.C. § 3729 *et seq*. in the name of and on behalf of the United States of America to recover treble damages and civil penalties arising from Defendants' fraudulent submission of false claims for payment to the Medicare program.

2. Defendants Cardiac Imaging, Inc. ("CII"), Samuel R. Kancherlapalli ("Kancherlapalli"), and Rick P. Nassenstein ("Nassenstein"), knowingly and willfully offered and/or paid kickbacks, primarily in the form of improper $500 per-patient referral fees disguised as "supervision" fees, to induce physicians to refer patients for Positron Emission Tomography

(PET) and cardiovascular stress tests at CII's mobile PET units. These illegal quid pro quo payments violate the federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b), and referrals to CII by recipients of the illegal kickbacks violate the Stark Law, 42 U.S.C. § 1395nn.

3. Defendants CII, Kancherlapalli, and Nassenstein also knowingly and willingly offered and/or paid illegal kickbacks to government healthcare program beneficiaries by routinely waiving or discounting the beneficiaries' copayments for PET procedures but nevertheless billing the government for 100 percent of the procedures' costs.

4. These illegal payments resulted in Defendants submitting false claims and statements to government healthcare programs in violation of the False Claims Act, in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq*.

5. Moreover, in some cases physicians paid to "supervise" PET and cardiovascular stress tests were not properly qualified to do so under Medicare regulations and carrier requirements, which only permit providers to bill Medicare for these procedures when supervised by certain licensed practitioners qualified to supervise the service. In other cases, the physicians were not even present during the procedures, and therefore could and did not provide the supervision as required by Medicare regulations. 42 C.F.R. § 410.33(b)(3). Defendants nevertheless knowingly billed Medicare for PET and cardiovascular stress tests performed without the requisite physician supervision, in violation of the False Claims Act.

II. PARTIES

6. The United States of America is the real party in interest in this matter.

7. Relator Lynda Pinto is an individual residing in Woodridge, Illinois. From July 2013 to December 2015 Ms. Pinto worked as a billing manager at Defendant Cardiac Imaging,

Inc., reporting directly to Defendants Samuel Kancherlapalli and Rick Nassenstein. She resigned in response to Defendants' fraudulent practices. Relator brings this action on behalf of herself and the United States pursuant to the False Claims Act, 31 U.S.C. § 3730(b).

8. The allegations set forth in this complaint are based on Ms. Pinto's direct, personal observations, as well as non-public documents in her possession. The facts and circumstances which give rise to Defendants' liability under the False Claims Act have not been publicly disclosed in any federal criminal, civil, or administrative hearing to which the government or its agent is a party; in a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation; or from the news media. 31 U.S.C. § 3730(e)(4)(A).

9. Ms. Pinto is the original source of the information upon which this complaint is based, *id.* at § 3730(e)(4)(B), and before filing the instant complaint, Ms. Pinto voluntarily served the United States Attorney with a full written disclosure of the information on which the allegations or transactions in this Complaint are based. Ms. Pinto has direct and independent knowledge about the claims alleged herein, and that knowledge is independent of and materially adds to any publicly-disclosed allegations or transactions.

10. Defendant Cardiac Imaging, Inc. is a private company providing mobile cardiac PET imaging services in Texas, Louisiana, Florida, Arizona, as well as, upon information and belief, New Jersey, Pennsylvania, Washington state, Washington DC, Maryland, New York, Oregon, California, and Nevada. The company was founded in 2012 and is headquartered at 2 Trans Am Plaza Drive, Suite 420, Oakbrook Terrace, IL. The company is incorporated in the state of Delaware and operates under the National Provider Identifier number 1770830606.

11. Defendant Samuel R. Kancherlapalli is an individual residing in Elmhurst, Illinois. Defendant Kancherlapalli is the president of Cardiac Imaging, Inc.

12. Defendant Rick P. Nassenstein is an individual residing in Bristol, Wisconsin. Defendant Nassenstein is the Chief Financial Officer of Cardiac Imaging, Inc.

I11. JURISDICTION AND VENUE

13. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This court also has jurisdiction pursuant to 28 U.S.C. § 1345 and 28 U.S.C. § 1331.

14. At all times material to this Complaint, Defendant CII regularly conducted substantial business within the State of Texas. Defendants are thus subject to personal jurisdiction in Texas.

15. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because CII transacts substantial business in this district and acts proscribed by 31 U.S.C. § 3729 occurred in this district.

IV. THE LAW

A. The Federal False Claims Act

16. The False Claims Act ("FCA") provides, in pertinent part, that any person who

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B)…
>
> * * *
>
> is liable to the Government for a civil penalty plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

31 U.S.C. § 3729(a)(1).

17. Pursuant to 28 C.F.R. § 85.3(a)(9), for FCA violations occurring on or before November 2, 2015, civil penalties range from $5,500 to $11,000. Pursuant to 28 C.F.R. § 85.5, penalties for FCA violations occurring after November 2, 2015 and assessed after January 29, 2018 range from $11,181 to $22,363. Civil Monetary Penalties Inflation Adjustment, 83 Fed. Reg. 3,944 (Jan. 29, 2018).

18. The False Claims Act provides that "knowing" and "knowingly" mean "that a person, with respect to the information, (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information[.]" 31 U.S.C. § 3729 (b)(1)(A). The False Claims Act does not require proof of specific intent to defraud. *Id.* at § 3729(b)(1)(B); *see also* 42 U.S.C. § 1320a-7b(h) (same).

19. A private person with information about an FCA violation may bring a *qui tam* action "for the person and for the United States Government." *Id.* at § 3730(b).

B. The Anti-Kickback Statute

20. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts the medical decision-making process and could result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The AKS was enacted in 1972 to "provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as

unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

21. In 1977, Congress amended the AKS to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the anti-kickback statute was to combat fraud and abuse in medical settings, which:

> [C]heats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs.

H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.

22. In 1987, Congress again strengthened the AKS to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

23. The AKS prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

24. The statute provides, in pertinent part:

> [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

25. "Kickbacks" have been defined to include payments, gratuities, and other benefits paid to physicians.

26. The AKS covers any arrangement where one purpose of the remuneration was to induce the referral of patients, even if the remuneration has another purpose as well. *See, e.g., United States v. Nagelvoort*, 856 F.3d 1117 (7th Cir. 2017); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985).

27. The AKS includes a safe harbor for personal services and management contracts, but this safe harbor does not apply if the payments take the volume or value of referrals into account, or if they are inconsistent with fair market value in arms-length transactions. 42 C.F.R. § 1001.952(d)(5).

28. In addition to criminal penalties, a violation of the AKS may also subject the perpetrator to exclusion from participation in federal health care programs, 42 U.S.C. § 1320a-7(b)(7), as well as civil monetary penalties of $50,000 per violation, 42 U.S.C. § 1320a-7a(a)(7), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

29. Compliance with the AKS is a precondition to participation as a health care provider under the federally-funded healthcare programs. In addition, compliance with the AKS is a material condition of payment for claims for which Medicare reimbursement is sought by medical providers.

30. In March 2010, the AKS was amended to explicitly state that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 § 6402(f) (2010) (codified as amended at 42 U.S.C. § 1320a-7b(g)). This provision applies to any service provided after July 1, 2010. *Id.*

31. Concerns about improper kickback arrangements between health care providers—including joint venture arrangements and waiver of Medicare Part B copayments and deductibles—have been the subject of Inspector General of the Department of Health and Human Services Special Fraud Alerts since the late 1980s. *See, e.g.,* Special Fraud Alerts, 59 Fed. Reg. 65,372 (Dec. 19, 1994) (reprinting the substance of 5 previously-issued special fraud alerts and specifically identifying improper referral arrangements between physicians and providers of diagnostic services).

32. Because the government would have paid nothing for PET and cardiovascular stress tests provided as the result of a kickback, the entire amount of the reimbursement payments made for those procedures constitutes damage to the government, *even if the services are otherwise medically necessary*: "AKS violations are not mere technicalities that the government would have forgiven in making reimbursement decisions." *U.S. ex rel. Kester v. Novartis Pharm. Corp.,* 43 F. Supp. 3d 332, 364 (S.D.N.Y. 2014).

C. The Stark Law

33. The Ethics in Patient Referrals Act, or "Stark Law," 42 U.S.C. § 1395nn, prohibits certain physician self-referral arrangements. Enacted in 1989 as an amendment to the Medicare statute, the Stark Law provides that the United States will not pay an entity for certain items or services (called "designated health services" or "DHS") referred by any physician having a "financial relationship" with the entity, unless the relationship satisfies an exception. *Id.* at §§ 1395nn(a)(1), (g)(1).

34. "Financial relationships" include "compensation arrangements" between the referring physician and the entity, 42 U.S.C. § 1395nn(a)(2)(B). "Compensation arrangements" are "any arrangement involving any remuneration between a physician . . . and an entity" other than forgiveness of certain amounts owed; the provision of certain items, devices, or supplies; and certain payments made by an insurer to a physician. *Id.* at § 1395nn(h)(1).

35. PET tests are "designated health services" within the meaning of the Stark Law. 42 U.S.C. § 1395nn(h)(6)(E), 42 C.F.R. § 411.351; *see also* Centers for Medicare & Medicaid Services, Code List for Certain Designated Health Services, *available at* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html (last visited July 12, 2018) (listing "heart image (pet)" codes 78491 and 78492 as designated health services).

36. The Stark law includes a safe harbor for personal services and management arrangements, but this safe harbor does not apply if the payments are volume-based or exceed fair market value. 42 U.S.C. § 1395nn(e)(3).

37. Compliance with the Stark law is a material condition of payment of Medicare claims.

38. Any person who collects funds billed in violation of the Stark law may be liable for civil money penalties and "shall refund on a timely basis. . . any amounts" collected in violation of the statute. *See* 42 U.S.C. § 1395nn(g)(2)-(3), 42 C.F.R. § 411.353(d).

D. The Medicare Program

39. In 1965, Congress enacted Title XVII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain healthcare services.

40. The Medicare Program is a federally-funded health insurance program that benefits the elderly, disabled, and those afflicted with end-stage renal disease. 42 U.S.C. § 1395 *et seq.*

41. Part B of Medicare pays claims submitted on behalf of Medicare beneficiaries by physicians and other health care practitioners and suppliers.

42. Medicare is not permitted to pay for any expense that is not "reasonable and necessary for the diagnosis and treatment of illness or injury." 42 U.S.C. § 1395(a)(1)(a). Regulations, national coverage determinations, and local coverage determinations specify services and devices that are covered as medically reasonable and necessary. Certain services and devices are excluded from coverage because they are not reasonable and necessary.

43. The U.S. Department of Health and Human Services ("HHS") is responsible for the administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMS") is an agency of HHS and is directly responsible for the administration of the Medicare Program. To administer Part B of the Medicare Program, CMS contracts with commercial entities (typically insurance companies) which are responsible for processing and paying claims (Medicare Administrative Contractors or "MACs"). 42 U.S.C. § 1395u.

44. Under the Medicare Program, CMS makes retrospective payments through its contractors to Medicare providers for patient services. A contractor will review and approve claims submitted for reimbursement by Medicare providers and makes payments on those claims which appear to be eligible for reimbursement under the Medicare Program.

45. To be eligible to submit claims to Medicare and obtain reimbursement, providers must enroll in the Medicare Program using either Form CMS-855B or the Internet-Based Provider Enrollment, Chain, and Ownership System (PECOS).

46. The 855B application form requires providers, including Defendants, to certify as follows:

> 3. I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> . . .
>
> 6. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Form 855B, Medicare Enrollment Application, Clinics/Group Practices and Certain Other Suppliers, §15(A), *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855b.pdf (last visited July 12, 2018).

47. The PECOS application must also be accompanied by a paper certification statement which requires substantially the same certifications as the 855 forms.

48. Once enrolled as a provider, most claims must be submitted electronically, and in order to do so, providers, including Defendants, are required to execute an Electronic Data Interchange ("EDI") Enrollment Agreement. These EDI agreements contain certifications to which all electronically-filed claims are subject, including the enrollee's certification that it will "submit claims that are accurate, complete, and truthful."

49. In signing the EDI Enrollment Agreement, providers, including Defendants, acknowledge that "all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under Medicare, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law."

50. Claims for Medicare reimbursement are submitted via paper or electronic versions of documents known as CMS 1500 forms. The CMS 1500 forms contain the patient's identifying information, the provider's unique Medicare number, and a description of the items and services provided for which reimbursement is sought, as identified by CPT and HCPCS codes.

51. In submitting claims for payment using CPT and HCPCS codes, providers, including Defendants, represent to Medicare that they have provided the services corresponding to the codes.

52. Further, in submitting the paper Form CMS-1500 or its electronic equivalent to Medicare or its contractors, the provider must certify that the information submitted is "true, accurate and complete." They must further certify that they have complied with Medicare laws, including the anti-kickback statute and Stark law:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license#, or SSN) of the primary individual rendering each service is reported in the designated section....

CMS Form 1500 at 2.

53. Medicare Part B generally pays 80 percent of the reasonable and necessary charges for medically necessary services provided to beneficiaries. 42. U.S.C. §§ 1395l(a)(1), 1395y(a)(1)(A). The remaining 20 percent copayment is owed by the beneficiaries themselves.

54. The purpose of the copayment is to incentivize beneficiaries to select and receive services that are medically necessary, as opposed to selecting services because they are free. *See* Special Fraud Alerts, 59 Fed. Reg. 65,372 at 65,375.

55. The routine waiver of copayments is prohibited by federal law, and providers may waive copayments only in very limited circumstances, *i.e.* after considering the patient's particular and specific financial hardship. *Id.* (citing 18 U.S.C. §§ 287, 1001; 31 U.S.C. § 3729; 42 C.F.R. § 1320a-7a); *see also* Medicare Program Integrity Manual, Ch. 4 § 4.22.1.1 ("Routine waivers of coinsurance or deductibles are unlawful because they could result in--1) false claims; 2) violation of the anti-kickback statute; and/or 3) excessive utilization of items and services paid for by Medicare.").

56. A provider that routinely waives copayments misstates its actual charges on its Medicare claim forms, and the claims are false as a result. Where, for instance, a supplier represents to Medicare that the charge for a procedure is $100, but routinely waives the 20 percent ($20) copay, the actual charge for the procedure is $80. Medicare should therefore be paying 80 percent of $80 ($64) to the provider based on this lower figure. If the provider misrepresents the actual charge to Medicare and collects 80 percent of $100 despite waiving the copay owed by the beneficiary, Medicare overpays the provider by $16.

57. Routine waivers of copayments violate the Anti-Kickback Statute by inducing patients to purchase more items or services from the providers and inducing physicians to refer Medicare patients to the providers.

E. Medicare Coverage of Independent Diagnostic Testing Facilities and Positron Emission Tomography (PET) Procedures

58. Medicare Part B pays for diagnostic procedures provided by Independent Diagnostic Testing Facilities (IDFTs), including mobile cardiac PET units like those operated by Defendants. *See* 42 C.F.R. §§ 410.32-33. IDTFs provide diagnostic procedures independent of physicians' offices or hospitals, and the patient's treating physician must order the diagnostic tests furnished by the IDTF. 42 C.F.R. §§ 410.33(a), (d).

59. Diagnostic testing services, including mobile cardiac PET and cardiovascular stress test services provided by Defendants, must be provided under the appropriate physician supervision, depending on the risk of harm to the patient associated with the specific test. Diagnostic testing services furnished without the required level of physician supervision are not reasonable and necessary. 42 C.F.R. §§ 410.32(b)(1), 410.33(b).

60. The levels of physician supervision for diagnostic testing services, including mobile cardiac PET and cardiovascular stress test services provided by Defendants, are set out in 42 C.F.R. § 410.32(b)(3) as follows:

> (i) *General supervision* means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
> (ii) *Direct supervision* . . . means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure . . .
> (iii) *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

See also Form 855B, Attachment 2, § E: Independent Diagnostic Testing Facilities, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855b.pdf.

61. Given their inherent risk of harm—including potential adverse or allergic reactions—Medicare requires direct supervision for certain tests, including diagnostic tests involving the injection of radioactive myocardial perfusion tracers and stress agents. *See infra* at ¶ 61. "[T]he IDTF's supervising physician must personally furnish this level of supervision[,]" 42 C.F.R. § 410.33(b)(2), and must do so "throughout the performance of the test." *Id.* at 410.33(b)(3).

62. Pursuant to Medicare regulations, in order to qualify to supervise services provided by IDTFs, physicians "must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF." 42 C.F.R. § 410.33(b)(2). Physicians' proficiency is documented either by certification in specific medical specialties or subspecialties, or by criteria established by the relevant Medicare carrier. *Id.*

63. Further, supervising physicians must certify that they "have the required proficiency in the performance and interpretation of each type of diagnostic procedure" listed on the Medicare application. Form 855B, Attachment 2, § E.

64. IDTFs must "maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished." 42 C.F.R. § 410.33(b)(2).

65. The Medicare Physician Fee Schedule Database and Medicare contractors' Local Coverage Determinations contain listings of the PET and related procedures, associated codes, and the level of physician supervision required for each.[1] As set out in 42 C.F.R. § 410.33(b)(2), Local Coverage Determinations also specify the credentials the supervising physicians must possess in order to have the "required proficiency in the performance and interpretation of each type of diagnostic procedure."[2] Relevant here, Defendant CII performs and bills Medicare for the following:

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[1] *See* Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, Section 80, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.PDF (last visited July 12, 2018) (setting out physician supervision requirements and assigning numerical levels for physician supervision requirements in the Medicare Physician Fee Schedule Database); Medicare Physician Fee Schedule Database, *available at* https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx (last visited July 12, 2018).

[2] Medicare's contractors specify the qualification requirements for supervising physicians, as well as the supervision levels. *See, e.g.,* Noridian Healthcare Solutions, Independent Diagnostic Testing Facility (IDTF) Physician and Technician Qualification Requirements, *available at* https://med.noridianmedicare.com/web/jeb/specialties/idtf/independent-diagnostic-testing-facility-idtf-physician-and-technician-qualification-requirements (last visited July 12, 2018); First Coast Service Options MAC – Part B Coding Guidelines, *available at* https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/33910_3/IndependentDiagnosticTestingFacility_codeguidePartB.3r.pdf (last visited July 12, 2018); Novitas Solutions, Local Coverage Article: Independent Diagnostic Testing Facility (IDTF) (A53252), *available at* https://www.cms.gov/medicare-

a. 78492: "Heart image (pet) multiple." The technical component[3] of this service must be performed under the general supervision of a physician, and the physician must be board certified in nuclear medicine, cardiology, or radiology.

b. 93017: "Cardiovascular stress test, tracing only, without interpretation and report." This service must be performed under the direct supervision of a physician, and the physician must be a board-certified internist or cardiologist.

66. IDTF claims for PET-scan-related reimbursement also include the following HCPCS codes: A9555, Rubidium Rb-82 (a radioactive myocardial perfusion tracer), per study dose, up to 60 millicuries; J2785, injection, regadenoson (a stress agent), .01mg.

67. Medicare's contractors must deny IDTF claims submitted in violation of the Stark law. *See* Medicare Claims Processing Manual, Chapter 35 – Independent Diagnostic Testing Facility (IDTF), Section 10.2, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c35.pdf (last visited July 12, 2018); *see also* Form CMS-855B at p. 31 (requiring applicants certify that "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with . . . the Federal anti-kickback statute and the Stark law").

V. FACTUAL ALLEGATIONS

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coverage-database/details/article-details.aspx?articleId=53252&ver=63&Cntrctr=319&ContrVer=1&CntrctrSelected=319*1&name=Novitas+Solutions%2c+Inc.+(12102%2c+A+and+B+MAC%2c+J+-+L)&s=11&DocType=Active&bc=AgAAAAIAAAAA& (last visited July 12, 2018).

[3] Diagnostic testing claims, including those for PET scans provided by mobile IDTFs, are billed using both a professional component (PC) and a technical component (TC). Medicare pays the former for services provided by the physician, including supervision interpretation, and a written report. Medicare pays the latter for services provided by non-physician personnel, as well as the provision of equipment, supplies, and other costs related to the test. Providers bill the professional component using the modifier "26," and the technical component using the modifier "TC."

68. Positron Emission Tomography (PET) myocardial perfusion stress tests (hereinafter to as "PET scans") are noninvasive nuclear imaging tests that use radioactive tracers and stress agents to detect heart disease. The tracer is injected into the patient, and the PET scanner produces an image showing the distribution of the tracer in the heart.

69. Defendants induce physicians to order these PET scans for Medicare patients by entering into sham "PET Medical Supervision Agreements" pursuant to which the physicians are paid $500 per patient, ostensibly to "supervise" the PET scans performed by CII, irrespective of whether the amount represents fair market value for the service or whether the physician is qualified to supervise the procedures according to Medicare rules. In fact, the payments are per-patient kickbacks disguised as "supervision" fees.

70. Defendants also induce physicians to order PET scans for Medicare patients by providing kickbacks to patients in the form of copay discounts and waivers. In some cases, Defendants reduce the amount owed to $250 as a "courtesy discount;" in other cases Defendants agreed to never collect any amounts owed from physicians' patients in order to induce the physicians to order Defendants' PET scan services.

71. Defendants provide further inducements to both referring physicians and Medicare beneficiaries in the form of American Express gift cards.

72. As a result of these kickbacks and financial arrangements, CII's claims for payment to Medicare were false and fraudulent.

A. Defendants Enter into Sham Supervision Agreements and Pay $500 Per-Patient Kickbacks to Physicians to Induce Them to Refer Medicare Patients

73. Since its inception, Defendant CII has paid physicians to refer Medicare patients for cardiac PET scans through the use of sham "Medical Supervision Agreements." Defendants

Kancherlapalli and Nassenstein personally negotiate, execute, and arrange performance and payment pursuant to these agreements.

74. Although these agreements purport to pay physicians $500 *per hour* spent providing direct and general supervision, in fact Defendants and their referring-physician customers agreed that the physicians would receive $500 *per patient* scanned.

75. While the supervision agreements state that the physicians are to provide direct and general supervision for CII's PET scans, upon information and belief, Defendant Kancherlapalli told physicians and their offices that CII, and not the physicians, would provide all required supervision for the PET scans. As a result, some of CII's physician customers decline to certify that they provide general or direct supervision to CII's patients on Attachment 2 to the CMS-855B forms submitted to Medicare. For these physicians' patients, no one has certified to Medicare that they provide the required supervision for their PET scans. In other cases, CII completed the forms to make it appear as if the physicians certified that they provide supervision, when in fact they did not.

76. Moreover, although the supervision agreements claim to pay the physicians $500 per hour, PET scan patients are rarely seen for a full hour, as evidenced by the physicians' own PET scan schedules (frequently scheduling exams 30, or even 15, minutes apart), CII's training materials (which state that "scan time is 25-35 minutes") and their website (which boasts that patients can be "in and out in less than 45 minutes").[4] Nevertheless, upon information and belief

[4] *See* Defendants' websites: https://www.mobilecardiacpet.com/ (last visited July 12, 2018); https://www.mobilecardiacpet.com/pet-mpi-statistics/ (listing PET scans as taking 30 minutes) (last visited July 12, 2018); https://www.mobilecardiacpet.com/case-study-number-three/) (listing PET exam time as 40 minutes) (last visited July 12, 2018; https://www.mobilecardiacpet.com/case-study-number-two/ (same) (last visited July 12, 2018).

and on Defendants' instruction, each physician uniformly invoiced and billed as if they supervised each and every patient for one hour.

77. Further, although the agreements claim that the $500 payment is "fair market value," the $500 fee is uniform for all geographic areas in which CII operates and for all physicians ordering and supposedly supervising the scans, regardless of whether they possess the requisite supervision credentials required by Medicare.

78. The $500 per-patient kickback payments are not consistent with fair market value, and do not reflect the value of comparable physician supervision services in the marketplace in arm's-length transactions by parties not in a position to refer to one another.

79. The aggregate payments to the physicians are not set in advance. Instead, they are volume-based payments—that is, Defendants' payments to physicians vary based on the number of patients receiving PET scans—paid by Defendants with the purpose and effect of inducing referrals of Medicare and other patients.

80. Defendants' per-patient kickbacks had the desired effect, inducing physicians to refer patients to CII for PET scans. They also constitute prohibited compensation arrangements between CII and referring physicians under the Stark Law.

81. According to an internal CII document tracking the number of patients scheduled, scanned, and cancelled by date and practice, CII scanned a total of 2,114 patients in Florida and Texas between June and November of 2015 alone. **Exhibit A.** Upon information and belief, and based on Ms. Pinto's personal knowledge and experience, Defendants paid the referring physicians $500 for each and every one of these 2,114 patients, for a total of $1,057,000. Also on information and belief, the vast majority of these patients were Medicare patients for whom CII claimed and received Medicare reimbursement.

82. Because all of Defendants' patients are procured as a result of illegal kickbacks and compensation arrangements that violate the Stark Law, all of CII's certifications on their CMS-1500 and 855B forms are false, and all of their claims to Medicare are false and fraudulent.

1. Specific Examples of Defendants' Fraudulent "Physician Supervision" Agreements

a. Tyler Internal Medicine Associates[5]

83. By way of example, Dr. Thomas Buzbee of Tyler Internal Medicine Associates ("TIMA") executed a physician supervision agreement with CII on April 15, 2013. The agreement purported to entitle Dr. Buzbee to $500 per hour for supervision services. In fact, the $500 fee was a per-patient kickback paid to Dr. Buzbee and TIMA in exchange for their referrals of patients to CII for PET scan services.

84. On May 1, 2013, Dr. Buzbee entered into a "Medical Diagnostic Service Agreement" with CII, Exhibit A to which required him to "schedule a minimum of 8 exams and a maximum of 10 exams" per day, at least one day per month.

85. Upon information and belief, TIMA and Dr. Buzbee began referring patients to CII for PET scans in exchange for the $500 per-patient kickbacks on or around March 24, 2014.

86. On July 21, 2014, for example, CII performed PET scans on 8 TIMA patients. According to the schedule TIMA provided to CII, the patients were scanned 30 minutes apart, for a total scan time of four hours.

87. On July 22, 2014 Elaine A. Riley, an administrative assistant for TIMA, wrote to Defendant Nassenstein transmitting TIMA's invoice associated with the scans. Instead of

[5] As set out below, the physicians at this practice were not qualified to supervise PET scans. *Infra* at V.B.

requesting payment for 4 hours of supervising PET scans ($2,000), the invoice requested $500 as the "unit price" *per patient* and a total balance due of $4,000.[6] *See* **Exhibit B** at p. 1.

88. That the $4,000 balance was a *per patient* bounty was confirmed by Defendant Nassenstein himself, when upon receipt of Ms. Riley's email he wrote to Relator that "She billed me for 8 [patients]. Thought we did 9." **Exhibit B** at p. 2.

89. Upon information and belief, these TIMA patients scanned on July 21, 2014 were Medicare patients for whom CII sought and received Medicare reimbursement.

90. On or about April 2015, Defendants began requiring that physicians and practices, including TIMA, list "1 hour" next to each patient on the invoices submitted to CII in order to disguise the per-patient payments as hourly supervision fees.

91. On April 20, 2015, for instance, TIMA had 5 patients scheduled to receive PET scans, but only 4 showed up and were scanned.

92. According to the schedule TIMA submitted to CII for these scans, Dr. Anthony Davis supervised 3 scans, 2 of which were scheduled 30 minutes apart, and another which was assigned a 15-minute time slot.

[6] Defendants did not require invoices until some time in mid-2014; before then—or when a physician failed to complete an invoice—Defendant Nassenstein calculated the per-patient kickback based solely on the number of patients on the PET schedule. As discussed below, to conceal their true nature and purpose, Defendants eventually required that invoices list "1 hour" next to each patient name.

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93.

Exam Date: Monday, April 20, 201[illegible]

PLEASE FAX ORDER BY: 5 DAYS PRIOR TO SERVICE

Fax To: 630.344.[illegible]

Exam: Myocardial PET Rest/Stress Perfusion Protocol: [X] Single Isotope; Rubidium 82 Pharmacological Agent: [X]

Practice/Physician Name: Tyler Internal Medicine Phone Number: 903.533.0644

Practice Address: 1910 Roseland Blvd Contact Person: Amanda Daniels

Tyler, TX 75701

Print all schedules in black ink only. ALL INFORMATION MUST BE FILLED IN

#	Appointment Time	Last Name	First Name	DOB	A	S	H	W	Patient ID	Doctor	Comments
1	9:00am	[redacted]	[redacted]	[redacted]	71	[redacted]			042015 1 1	Davis	
2	9:30am	[redacted]	[redacted]	[redacted]	77	[redacted]			042015 1 2	Davis	
3	10:00am	[redacted]	[redacted]	[redacted]	63	[redacted]			042015 1 3	Davis	CK
4	10:30am	[redacted]	[redacted]	[redacted]		[redacted]			042015 1 4	Villeda	
5	11:00am								042015 1 5		
6	11:30am								042015 1 6		
7	12:00pm								042015 1 7		
8	12:30pm								042015 1 8		
9	1:15pm								042015 1 9		
10	1:30pm								042015 1 10		
11	2:15pm	[redacted]	[redacted]	[redacted]	71	[redacted]			042015 1 11	Davis	
12	2:30pm								042015 1 12		

94. Upon receipt of the above schedule after the completion of the PET scans, Relator forwarded it to Defendants Kancherlapalli and Nassenstein so that they could calculate the $500 per-patient payment due to TIMA for scans performed that day.

95. TIMA and Dr. Davis billed CII $500 for "1 hour" for each of these patients, even though according to their own schedule they did not supervise the patients for more than 30 minutes at a time, for a total of 1 hour and 45 minutes.

96.

Tyler Internal Medicine Associates

DATE: 4/22/2015
INVOICE # 15

1910 Roseland Blvd.
Tyler, Tx
903-533-0644
903-533-0441

[redacted]

Cardiac Imaging
100 West Roosevelt Rd.
Building A1, Ste. 201
Wheaton, Illinois 60187

1. [redacted] - Davis - 1 hour		500.00
2. [redacted] - Davis - 1 hour		500.00
3. [redacted] - Villena - 1 hour		500.00
4. [redacted] - Davis - 1 hour		500.00
	SUBTOTAL	$ 2,000.00
OTHER COMMENTS	TAX RATE	0.0000
	TAX	$ -
	OTHER	$
Test date Monday April 20, 2015	TOTAL	$ 2,000.00

97. Defendant CII, upon information and belief, submitted claims for payment to Medicare for the PET scans provided to the 4 TIMA patients listed in the invoice and schedules above, and paid TIMA the $2,000 kickback associated with these patients' PET scans via check on May 22, 2015.

b. Dr. Neil Shechtman M.D., P.A.[7]

98. Upon information and belief, in May of 2015 Dr. Neil Shechtman, an internal medicine doctor in Lake Placid, FL, entered into a Medical Supervision Agreement with CII, entitling him to $500 per hour for supervising PET scans provided to patients he referred to CII. The $500 fee was actually a per-patient kickback paid to Dr. Shechtman in exchange for his referrals of patients to CII.

[7] As set out below, Dr. Shechtman was not qualified to supervise PET scans. *Infra* at V.B.

99. For example, on October 27, 2015, 12 of Dr. Shechtman's patients were scanned by CII. According to the schedule his office submitted, the scans were scheduled for 30 minutes each, from 9:15 A.M. until 4:45 P.M., with one lunch break from 11:45 A.M. until 12:45 P.M.[8] and another 30-minute break from 3:15-3:45 P.M.

100. Although the actual scan time scheduled for these patients was only 6 hours, Dr. Shechtman's October 28, 2015 invoice for these scans lists 12 hours of supervision, 1 hour for each patient, and requests payment of $6,000.

101. Had Defendants and Dr. Shechtman actually agreed that Dr. Shechtman would be paid for his time supervising PET scans, he should have been paid $3,000. Upon information and belief, however, CII paid Dr. Shechtman the $6,000 kickback for the 12 patients that received PET scans.

102. Defendant CII also, upon information and belief, submitted claims for payment to Medicare for the PET scans provided to these 12 patients.

c. Cardiology Center of Acadiana

103. By way of further example, on May 16, 2013, Dr. Michael Dibbs of Cardiology Center of Acadiana executed a physician supervision agreement with CII, which entitled him to $500 per hour for supervising PET scans provided to the patients he referred to CII. In fact, the $500 fee was a per-patient kickback paid to Dr. Dibbs in exchange for him referring patinets to CII for PET scan services.

[8] In Relator's experience, it was Dr. Shechtman's practice to schedule lunch for 1 hour in between scans.

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104. On the same day, Dr. Dibbs executed a Medical Diagnostic Service Agreement, Exhibit A to which required him to schedule a minimum of 8 exams and a maximum of 12 exams per day, at least twice a month.

105. Upon information and belief, Dr. Dibbs began referring patients to CII for PET scans in exchange for the $500 per-patient kickback on or around June 24, 2014.

106. For instance, Dr. Dibbs referred 9 patients for mobile PET scans at his Lafayette, LA practice on March 31, 2015. Ultimately, 7 were scanned, 45 minutes apart.

107.

Exam Date: Tuesday, March 31, 2015

PLEASE FAX ORDER BY 5 DAYS PRIOR TO SERVICE. Fax To: 630.344.092

Exam: Myocardial PET Rest/Stress Perfusion Protocol: X Single Isotope, Rubidium-82 Pharmacological Agent: X

Practice/Physician Name: Cardiology Center of Acadiana/Dr. Dibbs Phone Number: 337.984.9355

Practice Address: 121 Rue Louis XIV, Bldg. Suite B Contact Person: Mia/Julie

LaFayette, LA 70508

Print all schedules in black ink only. ALL INFORMATION MUST BE FILLED IN

#	Scheduled Time	Last Name	First Name	DOB	A	S	H	W	Patient ID	Doctor	Comments
1	9:30am	[redacted]	[redacted]	[redacted]	73	[redacted]			033115 1 1	Dibbs	completed
2	10:15am	[redacted]	[redacted]	[redacted]	58	[redacted]			033115 1 2	Dibbs	no show
3	11:00am	[redacted]	[redacted]	[redacted]	66	[redacted]			033115 1 3	Dibbs	cancelled
4	11:45am	[redacted]	[redacted]	[redacted]	71	[redacted]			033115 1 4	Dibbs	completed
5	12:30pm	[redacted]	[redacted]	[redacted]	84	[redacted]			033115 1 5	Dibbs	completed
6	1:15pm	[redacted]	[redacted]	[redacted]	79	[redacted]			033115 1 6	Dibbs	completed
7	2:00pm	[redacted]	[redacted]	[redacted]	74	[redacted]			033115 1 7	Dibbs	completed
8	2:45pm	[redacted]	[redacted]	[redacted]	50	[redacted]			033115 1 8	Dibbs	completed
9	3:30pm	[redacted]	[redacted]	[redacted]	85	[redacted]			033115 1 9	Dibbs	completed
10	4:15pm								033115 1 10		

108. CII, upon information and belief, submitted claims for payment to Medicare for the PET scans performed on these patients.

109. Dr. Dibbs requested payment of $500 for each of the 7 patients scanned on March 31, 2015, and, upon information and belief, CII paid him a $3,500 kickback for these patients on May 12, 2015.

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d. The Heart and Vascular Specialists

110. Similarly, on July 25, 2013, Dr. Shashikumar ("Shashi") Bellur of Shashi S. Bellur, M.D. P.A., d/b/a The Heart and Vascular Specialists of Conroe, Texas executed a physician supervision agreement with CII, which entitled him to $500 per hour for supervising PET scans provided to the patients he referred to CII. The $500 fee was actually a per-patient kickback paid to Dr. Bellur in exchange for his referrals of patients to CII for PET scan services.

111. Upon information and belief, Dr. Bellur began referring patients to CII for PET scans in exchange for the $500 per-patient kickbacks in 2014.

112. On April 15, 2015, for instance, Dr. Bellur scheduled 8 patients for PET scans with CII, but only 7 received scans. All but one patient were allotted 45-minute time slots between 9 A.M. and 2:30 P.M., with one cancellation from 9:45-10:30 A.M.

113.

Exam Date: Wednesday, April 15, 2015

PLEASE FAX ORDER BY: 5 DAYS PRIOR TO SERVICE. Fax To: 630.344.0923

Exam: Myocardial PET Rest/Stress Perfusion Protocol: [X] Single Isotope; Rubidium-82 Pharmacological Agent: [X] Le

Practice/Physician Name: Dr. Bellur/Heart & Vascular Specialist Phone Number: 936.756.8484

Practice Address: 600 River point Drive Ste 101 Contact Person: Pam

Conroe, TX 77304

Print all schedules in black ink only. ALL INFORMATION MUST BE FILLED IN

#	Scheduled Time	Last Name	First Name	DOB	A	S	H	W	Patient ID	Doctor	Comments
1	9:00am	[redacted]	[redacted]	[redacted]	71	[redacted]			041515 1 1	Bellur	
2	9:45am	[redacted]	[redacted]	[redacted]	76	[redacted]			041515 1 2	Bellur	Cx
3	10:30am	[redacted]	[redacted]	[redacted]	78	[redacted]			041515 1 3	Bellur	
4	11:15am	[redacted]	[redacted]	[redacted]	84	[redacted]			041515 1 4	Bellur	
5	12:00pm	[redacted]	[redacted]	[redacted]	83	[redacted]			041515 1 5	Bellur	
6	1:00pm	[redacted]	[redacted]	[redacted]	69	[redacted]			041515 1 6	Bellur	
7	1:45pm	[redacted]	[redacted]	[redacted]	79	[redacted]			041515 1 7	Bellur	
8	2:30pm	[redacted]	[redacted]	[redacted]	67	[redacted]			041515 1 8	Bellur	

114. CII on-site staff sent Relator the completed schedule after the scans were finished on April 15, 2015, and she promptly forwarded it—along with the total number of patients scanned—to Defendants Kancherlapalli and Nassenstein so that they could calculate the per-patient payment owed to Bellur based on the volume of his referrals for PET scans on that date.

115. According to that schedule, Dr. Bellur did not supervise PET scans for 7 hours on April 15, 2015; his patients were scanned for a total of 5.5 hours.[9] On information and belief, CII nevertheless paid Dr. Bellur the $500 per-patient, $3,500 total kickback on May 13, 2015.

116. CII, upon information and belief, submitted claims for payment to Medicare for the PET scans provided to Dr. Bellur's patients on April 15, 2015.

B. CII Paid "Supervision" Fees to Physicians Who Are Not Qualified to Supervise PET Scans

117. In some cases, the physicians to whom CII pays sham "supervisor" fees in exchange for patient referrals are not even qualified to supervise PET scans according to Medicare rules. Most of these physicians nevertheless completed the IDTF attachment to Form CMS 855B, falsely certifying that they "have the required proficiency in the performance and interpretation of each type of diagnostic procedure" they were supposedly supervising. *See supra* at ¶ 63.

118. Defendant CII billed and was paid for PET scans performed without the physician supervision required by Medicare. Because PET scans performed without the required physician supervision are not reasonable and necessary, and therefore not payable by Medicare, all of CII's claims for payment for scans supposedly supervised by unqualified physicians are false and fraudulent. 42 U.S.C. § 1395(a)(1)(a); 42 C.F.R. § 410.32(b).

119. For example, Tyler Internal Medicine Associates, P.A., is (as the name suggests) staffed by internal medicine doctors, who were not certified in nuclear medicine, cardiology, radiology, or even in internal medicine.

[9] Or fewer: on information and belief, Dr. Bellur left the premises at 3 P.M. on scan days.

120. Dr. Buzbee of Tyler Internal Medicine Associates has never been board certified in nuclear medicine, cardiology, or radiology; he was board certified in internal medicine in 1994 and again in 2004, but is not currently, and was not so certified when he billed for and received sham "supervision" payments from CII.

121. Dr. Anthony Davis of Tyler Internal Medicine Associates has never been board certified in nuclear medicine, cardiology, or radiology; although he was board certified in family medicine by the American Board of Family Medicine in 2007, he was not recertified in 2014 when his initial seven year certification period lapsed, and board certification in Family Medicine is insufficient to supervise PET scan services under Medicare rules.

122. Nevertheless, as set out above, CII billed Medicare for PET scans supposedly supervised by Drs. Buzbee and Davis. Because these physicians were not qualified to supervise the scans, all of these claims for payment were false and fraudulent.

123. Likewise, Florida's Dr. Neil Shechtman is an internal medicine doctor, who has never been board certified in nuclear medicine, cardiology, radiology, or internal medicine.

124. CII nevertheless paid Dr. Shechtman sham "supervision" fees in exchange for referring patients to receive PET scans, and, on information and belief, they nevertheless billed Medicare for PET scans he supposedly supervised. Because Dr. Shechtman is not qualified to supervise the scans, all of these claims for payment were false and fraudulent.

C. CII Paid "Supervision" Fees to Physicians Who Were Not Physically Present to Supervise PET Scans

125. CII's claims for payment for its PET scan services are false and fraudulent on the additional ground that in many instances, physicians were not even physically present in their office during the performance of the procedure.

126. In the case of Dr. Baxter Montgomery of Montgomery Heart and Wellness and the Houston Cardiac Association, he was regularly absent when CII was scanning his patients, especially on Fridays, when he was usually absent before noon, and sometimes was absent all day. Indeed, Julie Raffin, CII's CNMT who performed the scans, repeatedly contacted Defendants Nassenstein and Kancherlapalli to complain about Dr. Montgomery not being in the office when CII scanned his patients.

127. Defendants nevertheless regularly scheduled Dr. Montgomery's patients to be scanned on Fridays, knowing that he was absent and no one else was present to supervise the patients' PET scans. In fact, Dr. Montgomery's patients were scheduled to be scanned nearly every other Friday from at least October 17, 2014 through September 2015.

128. Upon information and belief, CII billed Medicare for these scans despite knowing that they were not supervised, and paid Dr. Montgomery $500 for each patient scanned.

129. In one instance, on Thursday, November 13, 2014, Relator spoke with Dr. Montgomery's nurse practitioner ("NP") to discuss the schedule for the next day. The NP told Relator that Dr. Montgomery would not be in the office that day, but that she (the NP), would be present to supervise the scans.

130. Relator explained to the NP that she was not qualified to supervise the scans, and immediately contacted Defendants Nassenstein and Kancherlapalli to inform them of Dr. Montgomery's absence and Relator's decision to cancel the scans scheduled for the following day.

131. Defendants Nassenstein and Kancherlapalli each responded that Dr. Montgomery found another doctor to cover for him, but Dr. Montgomery's office refused to respond to Relator's requests that the new doctor complete the IDTF attachment to CMS Form 855b as required by

Medicare. Ms. Raffin later confided to Relator that she was certain that no physician was present while patients were scanned on November 14, 2014.

132. Upon information and belief, CII nevertheless billed Medicare for the 10 patients scanned that day, and paid Dr. Montgomery $500 for each patient.

133. Similarly, Relator was specifically told that Dr. Shashikumar ("Shashi") Bellur left his office at 3 P.M. on scan days. Nevertheless, on several occasions his office scheduled patients for scans at or after 3 P.M., including on April 29, 2015; May 27, 2015; June 10, 2015; July 8, 2015; August 19, 2015; September 16 and 30, 2015; October 14, 2015; and November 11, 2015.

134. On information and belief, although Dr. Bellur was not present to supervise the scans that took place at or after 3 P.M., CII nevertheless paid him $500 per patient and billed and received payment from Medicare for these unsupervised PET scans.

D. Defendants Routinely Waive Beneficiary Copayments to Induce Referrals and Increase Utilization of Their PET Scan Services

135. In order to induce referrals, Defendants also routinely and indiscriminately waived beneficiaries' copayments or greatly discounted them, all the while billing Medicare for 100 percent of cost of the PET scan procedures, knowingly and willfully misrepresenting the actual costs of the procedures to the government and its contractors. These waivers or discounting of copayments violate the Anti-Kickback Statute, and rendered Defendants' related claims for payment to Medicare false and fraudulent.

136. A Medicare patient with no secondary or supplemental insurance is responsible for a 20 percent copay, which is generally over $400 for the PET scans at issue here.

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137. On or about July 2014, Defendants Nassenstein and Kancherlapalli instructed Relator to inform their biller, Diana Hermanson, to reduce Medicare patients' copays to $250 as a "nice gesture" to keep physicians happy.

138. Relator told Nassenstein that this violated Medicare rules, but he insisted on the practice.

139. Defendants also instructed Ms. Hermanson to implement the practice with private pay patients.

140. For example, according to the schedule submitted to CII, on June 3, 2015, CII scanned 7 patients of Dr. M. Akram Khan of the Cardiac Center of Texas, including that of Medicare Patient JP.

141. According to the billing statement sent to Patient JP on October 1, 2015, Defendant CII billed Medicare's Texas contractor, Novitas, the full charge for the PET scan, a total of $9,100. Novitas paid $2,140.34, and after CII applied the required adjustment, the patient's balance should have been $537.27. Defendants, however, made a "courtesy" adjustment of $287.27 to bring Patient JP's balance down to $250.

142.

78492 NUC SCANM-CARDIOPET MULTIPLE		7,000.00	
A9555 RUBIDIUM RB 82 DIAG PR STY DOS UP		1,300.00	
93017 STRESS TEST CARDIO TRACING ONLY		200.00	
J2786 INJECT REGADENOSON 0.1 MG		600.00	
NOVITAS SOLUTIONS PAYMENT		-2,140.34	
ADJUSTMENT		-6,413.65	
CO-INSURANCE TO SECONDARY			
UMR PAYMENT		-8.74	
CO-INSURANCE TO PATIENT: $537.27		-537.27	537.27
ADJUSTMENT COURTESY			-287.27
	TOTAL BALANCE		250.00

143. This "courtesy" adjustment violates the Anti-Kickback Statute, and renders CII's claim for payment for JP's PET scan false and fraudulent.[10]

144. Defendants also offered this "offset" to physicians for their out of network patients. As Defendant Nassenstein instructed Relator to explain to staff at the Healing Hearts Clinic on September 17, 2014, "if a patient with commercial insurance has an in-network benefit of 80%/20%, and out of network 60%/40%, he [Nassenstein] would be willing to offset the 20% difference between the two. Ultimately, the patient would be responsible for the in-network balance as if it were contracted with their insurance."

145. With the understanding that their patients would not be charged the full copay amount, Healing Hearts physicians thereafter referred both Medicare and private-pay patients to Defendants for PET scans, and were paid $500 per patient for each referral, as evidenced in these emails between Healing Hearts, Relator, and Defendant Nassenstein:

146.

From: Rick Nassenstein [mailto:RickN@edmaccess.com]
Sent: Tuesday, November 04, 2014 9:29 AM
To: Lynda Pinto
Subject: RE: Cardiac Imaging Inc. PET Scheduling

Yes. It should say 10/7/14 supervisor fees on the remittance.

From: Lynda Pinto [mailto:lyndap@edmaccess.com]
Sent: Tuesday, November 04, 2014 8:19 AM
To: Rick Nassenstein
Subject: FW: Cardiac Imaging Inc. PET Scheduling

Pls see below from HH clinic
10/7/14 we scanned 5 patients, so I'm assuming the $2500 is for the 1st scan date?

From: Christine [mailto:Christine@healingheartsclinic.com]
Sent: Monday, November 03, 2014 4:26 PM
To: 'Lynda Pinto'
Subject: RE: Cardiac Imaging Inc. PET Scheduling

Good Afternoon Lynda,

We received a check in the amount of $2500.00 check # 6000607. There are no patients names/dates of service's to apply these payments to. Can you check into this for me?

[10] The claim for payment is also false and fraudulent because, on information and belief, Defendants payed Dr. Khan a $500 kickback for referring JP to CII for a PET scan.

147. In order to secure the business of at least one physician, Defendants actually agreed to waive patients' copays in their entirety: upon information and belief, on or about March 2014 Defendant Kancherlapalli told Dr. Dibbs that CII would not bill his patients a copay at all, and would instead just accept Medicare or other insurance payment as payment in full.

148. As a result, Dr. Dibbs became one of CII's best customers, and on information and belief he received at least the following payments from CII in exchange for patient referrals: $4,000 on 07/21/2014; $3,000 on 07/29/2014; $9,000 on 11/21/2014; $4,500 on 12/19/2014; $4,000 on 01/06/2015; $5,000 on 01/20/2015; $4,000 on 01/30/2015; $3,500 on 05/12/2015; and. $3,000 on 07/02/2015.

149. CII, on information and belief, billed Medicare the full amount for the PET scans performed on Dr. Dibbs' patients.

E. Defendants Pay Other Kickbacks to Induce Referrals and Reward High-Volume Referrers

150. In addition to "supervision" fees, Defendants also paid physicians remuneration in the form of gifts based on their referral volume.

151. In December 2014, for example, Defendant Kancherlapalli asked Relator to determine which doctors referred the most patients to CII between March 1, 2014 and December 5, 2014 so that he could give them Christmas gifts based on their referral volume.

152. Pursuant to his instructions, Relator requested this information from Defendants' biller, Diana Hermanson of Rapid Reimbursement Services, Inc., and, upon information and belief, Defendant Kancherlapalli used it to pay the physicians holiday gifts in the form of American Express gift cards or cash.

153. Defendants also provided gift cards directly to patients, including Medicare beneficiaries. In Relator's experience, and on her information and belief, Defendants Nassenstein and Kancherlapalli instructed CII's on-site clinical staff to provide gift cards to dissatisfied patients who might complain to the referring physicians.

154. On information and belief, CII began sending patients American Express gift cards on or shortly after April 14, 2014. On that day, CII was scheduled to scan six patients at Tyler Internal Medicine Associates, but had to cancel each scheduled scan due to technical difficulties with the camera. This was the second time in as many weeks that CII had to cancel PET scans at Tyler Internal Medicine Associates.

155. Upon information and belief, TIMA threatened to pull out of their agreement with Defendants and quit using CII to provide PET scans. To keep the account, Defendant Kancherlapalli told Relator and Defendant Nassenstein to tell the site's administrator that CII would still pay the doctor the "supervision" fee of $500 per patient, even though no patients were scanned on that day.

156. Defendant Kancherlapalli also instructed Relator to mail each patient a $50 American Express gift card after she called each one to apologize and to tell them to expect the gift card in the mail.

157. On information and belief, after this incident Defendants Kancherlapalli and Nassenstein kept gift cards in each of CII's mobile PET trucks for clinical staff to give to dissatisfied patients who might complain or speak negatively about CII to referring physicians.

158. On November 6, 2015, for instance, Healing Hearts patient A.M. was scheduled for a PET scan at 12:30. Upon information and belief, A.M. was a Medicare patient, and he complained about his PET scan experience.

159. Upon learning of A.M.'s complaint, on November 9, 2015 Defendant Nassenstein instructed Relator to call A.M. regarding his complaint, and told her to instruct William Odom, the Certified Nuclear Medicine Technologist present during A.M.'s PET scan, to send the patient one of the American Express gift cards from his truck. On information and belief, Mr. Odom sent the gift card to the patient.

160. As with the other inducements Defendants paid to physicians and patients, these payments violate the Anti-Kickback Statute, and render CII's claims for payment to Medicare false and fraudulent.

COUNT ONE

(False Claims Act: Presentation of False Claims)

(31 U.S.C. § 3729(a)(1)(A))
(all Defendants)

161. Relator re-alleges and incorporates the allegations in paragraphs in all previous paragraphs as if fully set forth herein.

162. By virtue of the acts described above, from at least 2014 through, upon information and belief, the present, Defendants knowingly presented, or caused to be presented, false and fraudulent claims for payment or approval to the United States through the Medicare program, including those claims for reimbursement for services resulting from violations of the Anti-Kickback Statute and Stark Law, as well as services that were not supervised by qualified personnel.

163. Defendants presented or caused these claims to be presented with actual knowledge of their falsity, with reckless disregard of whether or not they were false, or with deliberate ignorance of whether or not they were false.

164. The government, unaware of the falsity of Defendants' records, statements, and claims for payment, paid and continues to pay the claims.

165. By virtue of Defendants' conduct, the United States has been damaged, and continues to be damaged, in an amount to be determined at trial, plus the maximum civil penalty per violation.

COUNT TWO

(False Claims Act: Presentation of False Statements or Records Material to False Claims)
(31 U.S.C. § 3729(a)(1)(B))
(all Defendants)

166. Relator re-alleges and incorporates the allegations in paragraphs in all previous paragraphs as if fully set forth herein.

167. By virtue of the acts described above, from at least 2014 through, upon information and belief, the present, Defendants knowingly made, used, or caused to be made or used a false record or statement material to a false or fraudulent claim for payment to the United States through the Medicare program, including false certifications and representations made when submitting false claims for payment for services resulting from violations of the Anti-Kickback Statute and Stark Law, as well as services that were not properly supervised by qualified personnel.

168. Defendants' false records or statements were material to government's decision to approve and pay the claims.

169. Defendants' false records or statements were made for the purpose of receiving payment for false or fraudulent claims, and were presented with actual knowledge of their falsity, with reckless disregard of whether or not they were false, or with deliberate ignorance of whether or not they were false.

170. By virtue of Defendants' conduct, the United States has been damaged, and continues to be damaged, in an amount to be determined at trial, plus the maximum civil penalty per violation.

COUNT THREE

(False Claims Act: Conspiracy)
(31 U.S.C. § 3729(a)(1)(C))
(all Defendants)

171. Relator re-alleges and incorporates the allegations in paragraphs in all previous paragraphs as if fully set forth herein.

172. By virtue of the acts described above, Defendants knowingly conspired, and upon information and belief, continue to conspire with each other and physicians to commit acts in violation of 31 U.S.C. §§ 3729(a)(1)(A) & (B). Defendants and these physicians committed overt acts in furtherance of this conspiracy as described above.

173. As a result of Defendants' conduct, the United States has been damaged, and continues to be damaged, in an amount to be determined at trial, plus the maximum civil penalty per violation.

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully requests this Court to enter judgment against Defendants, jointly and severally, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged within this Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* provides;

(b) That civil penalties be imposed for each and every false claim that Defendants presented or caused to be presented to the United States;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Court grant permanent injunctive relief to prevent any recurrence of violations of the False Claims Act for which redress is sought in this Complaint;

(e) That the Relator be awarded the maximum percentage of any recovery allowed to her pursuant the False Claims Act, 31 U.S.C. §3730(d)(1),(2);

(f) That this Court award such other and further relief as it deems proper.

DEMAND FOR JURY TRIAL

Relator, on behalf of herself and the United States, demands a jury trial in this case.

Dated: August 3, 2018

Respectfully submitted,

UNITED STATES OF AMERICA
ex rel. Lynda Pinto

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